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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,412	07/25/2001	Jacob Bar-Tana	23117-0002 DIV 1	8876

7590 06/13/2003

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/13/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/915,412

Applicant(s)

BAR-TANA, JACOB

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-9 and 21-31 is/are pending in the application.
- 4a) Of the above claim(s) 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>10</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

1. The amendment filed March 24, 2003 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 3, 4 and 10-20 have been canceled.
 - (B) Claims 1 and 8 have been amended.
 - (C) Comments regarding the Office Action have been provided drawn to:
 - (a) 112, 1st paragraph rejection, which has been withdrawn;
 - (b) 112 2nd paragraph rejection, which has been withdrawn;
 - (c) 103(a) rejection, which has been maintained for the reasons of record.
2. Claims 1, 2, 5-9 and 21-31 are pending in the case; Claims 21-31 have been withdrawn from consideration as being directed to a non-elected invention.
3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

4. Applicant's election without traverse of Group I, Claims 1-9, in Paper No. 12 is acknowledged.

Claim Rejections - 35 USC § 112, First Paragraph

5. Claims 1, 2 and 5-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants amended Claim 1 to indicate that the "heteroatoms are selected from the group consisting of nitrogen, oxygen and sulfur". However, the instant specification does not support this passage since there is no indication in the instant specification that the heteroatoms thereof are selected from nitrogen, oxygen and sulfur atoms. Hence, the instant specification does fulfill the requirements of the first paragraph of 35 U.S.C. 112, which requires that the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. The insertion into Claim 1 the passage "selected from the group consisting of nitrogen, oxygen and sulfur," raises the issue of new matter, which is improper under the first paragraph of 35 U.S.C. 112 and renders Claims 1 and dependent Claims 2 and 5-9 improper.

6. Applicant's arguments with respect to claims 1, 2 and 5-9 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

7. Claims 1, 2 and 5 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Hertz et al ("Mode of Action of Peroxisome Proliferators as Hypolipidemic Drugs – Suppression of Apolipoprotein C-III", The Journal of Biological Chemistry, Vol. 270, No. 22, Issued June 2, pp. 13470-13475, 1995) for the reasons disclosed on page 5 of the Office Action mailed September 16, 2002.

8. Claims 1, 2 and 7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Tana (US Patent No. 4,689,344) for the reasons disclosed on pages 5 and 6 of the Office Action mailed September 16, 2002.

9. Claims 1 and 6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Copper et al (US Patent No. 4,954,487) for the reasons disclosed on pages 6 and 7 of the Office Action mailed September 16, 2002.

10. Claims 1, 2, 8 and 9 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al (US Patent No. 5,502,226) for the reasons disclosed on pages 7 and 8 of the Office Action mailed September 16, 2002.

Arguments

11. Applicant's arguments filed March 24, 2003 have been fully considered but they are not persuasive. On page 6 of Applicants response, Applicants argue against the rejection of the claims on the grounds that the cited art does not teach or suggest activity under conditions where the liver is non-responsive to PPAR. Applicants argue that the requirement for CoA-thioesterification leading to suppression of HNF4 activity is neither a process limitation nor an indication of use, but a mandatory characteristic for

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activity in PPAR non-responsive species, namely humans. This argument is not persuasive because the arguments presented by Applicants are directed to intended use of the claimed pharmaceutical compositions. The claims are not directed to activity in humans.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., activity in PPAR non-responsive species) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants have not distinguished the instantly claimed pharmaceutical composition from the compositions of the prior art. Applicants are reminded that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01

Summary

12. Claims 1, 2 and 5-9 are rejected; Claims 21-31 are withdrawn from consideration.

Reply to Final Must Include Cancellation

13. This application contains claims 21-31 drawn to an invention nonelected without traverse in Paper No. 12. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information


15. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


E. White


JAMES O. WILSON
PRIMARY EXAMINER
Technology Center 1600